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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,796	02/20/2004	Brian Barney	NHC0071-USA	7178

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IVAX CORPORATION
4400 Biscayne Boulevard
Miami, FL 33137

EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/783,796

Applicant(s)

BARNEY ET AL.

Examiner

Annette F. Dixon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 26-29, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 17-25, 30-32, 35 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in Great Britain on February 20, 2003. It is noted, however, that applicant has not filed a certified copy of the 0303870.0 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specifically, Applicant has listed the following patent documents with in the specification; however, has not listed these documents on an information disclosure statement: US 5,503,144 and US 6,655,381.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 6-9, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Brunnberg et al. (6,880,555).

As to Claim 1, Brunnberg discloses a dry powder inhaler, comprising: a housing (10) having a mouthpiece (12) and a delivery passageway (14) connected to the mouthpiece; a magazine (80) positioned within the housing (10) and including a plurality of reservoirs (78) for holding doses of dry powder, and wherein the magazine (80) is movable within the housing (10) so that the reservoirs (78) are sequentially positioned within the delivery passageway of the housing (10) upon movement of the magazine (80); a cover (16) connected to the housing (10) and selectively movable to open and close access to the mouthpiece of the housing (10); and a rake (68) connected to the cover (16), extending into the housing (10) and engageable with the magazine (Column 6-Line 56 thru Column 7, Line 6) so that, upon the cover being moved to open the mouthpiece, the rake (68) moves the magazine (80) and causes one of the reservoirs (78) of the magazine (80) to be positioned within the delivery passageway (14). (Figures 1-4).

As to Claim 6, Brunnberg discloses the magazine (80) is annular and rotatably movable such that rotation of the annular magazine (80) sequentially positions the

plurality of the dry powder reservoirs (78) within the delivery passageway (14) of the housing (10). (Figure 1).

As to Claim 7, please see the rejection of claim 6. Regarding the single direction, Applicant is directed to Figure 1 showing the a clock-wise arrow on wheel (70).

As to Claim 8, as shown in Figures 3 and 4, the movement of the cover results in an engagement of the teeth (76) via elements 60, 58, 64, 56, to the rake (68).

As to Claim 9, as best shown in figure 4, the rake (68) is pivotally connected to the cover (16) and the cover is pivotally connected to the housing (10).

As to Claim 11, Brunnberg discloses dry powder medicament is contained within the reservoirs (78) of the magazine (80). (Column 6, Lines 15-20).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-5, 12-16, 26-29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunnberg et al. (6,880,555) in view of Rose et al. (5,441,060).

As to Claim 2, Brunnberg discloses all the elements of the dry powder inhaler; yet, does not expressly disclose the reservoirs of the magazine to be covered in a substantially moisture-resistant and air-tight manner prior to being inserted into the housing of the inhaler. However, at the time the invention was made, the formation of a

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magazine with a moisture-resistant and air-tight seal was well known. Specifically, Rose teaches the use of a foil and polymer coating in the formation of a blister pack to provide an effective oxygen and moisture barrier. (Column 9, Line 63-70). Further, as known in the art, humidity and oxidation effect the efficacy of the medicament; therefore, to prevent efficacy loss, medicaments have been known to be treated to extend the shelf-life of the medicament. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Brunnberg to include the moisture-resistant and airtight seal to prevent a loss of drug efficacy. (Figure 9).

As to Claim 3, please see the rejection of claim 2.

As to Claims 4 and 27, please see the rejection of claim 2.

As to Claims 5 and 26, Brunnberg teaches a sharp edge (24) used to remove the foil from the reservoir.

As to Claims 12 and 29, as shown in Figure 9 of Rose, the dose magazine has a bore (represented by the circular region) extending from the lower surface (represented by element 72) and an upper surface (represented by element 74) wherein the layers are moisture-resistant and airtight.

As to Claim 13, please see the rejection of claim 12, wherein the medicament is located within the circular region.

As to Claim 14, please see the rejection of claim 14, though Rose does not expressly disclose the layers to be secured with an adhesive; however, the very

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essence of an air-tight and moisture resistant seal requires a firm seal between the two layers.

As to Claim 15, please see the rejection of claim 2, the essence of an air-tight and moisture-resistant seal provides a lining protecting the medicament held within the reservoir.

As to Claim 16, please see the rejection of claim 2, the dome or bore (represented by the circular region, Figure 9 of Rose), intrinsically forms a trough wherein the medicament is protected via a moisture-resistant and air-tight seal.

As to Claim 28, please see the rejection of claim 6.

As to Claim 33, please see the rejection of claim 1.

As to Claim 34, please see the rejection of claim 7.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brunnberg et al. (6,880,555) in view of Nesbitt (7,093,595).

As to Claim 10, Brunnberg discloses a dry powder inhaler comprising all the elements of claim 10; yet, does not expressly disclose an indicator for indicating the number of doses remaining. However, at the time the invention was made the use of an indicator for measuring the number of doses remaining was well known. Specifically, Nesbitt teaches the use of a counter for determining the amount of medicament left for inhalation treatments; thereby enabling the user to determine if additional medicament is required prior to the next treatment. (Background). Therefore, it would have been obvious to one having ordinary skill in the art to modify the device of Brunnberg to

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include the counter of Nesbitt, to insure the patient knew the number of treatments that could occur prior to requiring additional medicament.

Allowable Subject Matter

8. Claims 17-25, 30-32, 35 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


TEENA MITCHELL
PRIMARY EXAMINER


Annette F Dixon
Examiner
Art Unit 3771
December 21, 2006